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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,010	09/08/2004	Susumu Kuwabata	43888-332	8864

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EXAMINER	
MARTIN, PAUL C	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,010	KUWABATA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 04/03/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/08/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Regarding the NPL Satoshi Iino reference in the 1449, the reference was not considered as it was not in conformance with 37 CFR 1.98 of the MPEP which states:

a) Any information disclosure statement filed under § 1.97 shall include the items listed in paragraphs (a)(1), (a)(2) and (a)(3) of this section.

(3) (i) A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein.

(ii) A copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c).

As there was no explanation of the references' relevance or English-language translation provided, the reference was not considered. A new PTO-1449 with the considered references initialed and the reference lined through and designated "not considered" has been provided. The Kuwabata reference was included in the Applicant's submitted IDS under the heading "The 68th Convention of the Electrochemical Society of Japan Lecture Summary" and therefore does not need to be made of record on the PTO-892.

It is noted in the newly amended claims 5 and 6 and amendments to the Specification filed 04/04/06 that the change of the equation $E_{cen}>E_{min}-5(V)$ to $E_{cen}>E_{min}-0.05(V)$ appears to correct a typo as the value of 0.05(V) is supported by Lines 16-18 of the original Specification.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda *et al.* (U.S. 6,340,428 B1).

This rejection is maintained for reasons of record set forth in the paper mailed 01/03/06, repeated below:

Ikeda *et al.* discloses a method for quantitating a substrate in a sample solution, which may contain dissolved interfering substances using an electrode system and a reagent system, comprising the steps of:

Supplying a sample solution containing substrate and potential interfering substances to an electrode system comprising a working electrode and counter electrode under a reaction layer containing oxidoreductase (glucose oxidase) and an electron mediator; applying an potential to the working electrode to cause a redox reaction of the electron mediator; measuring the electric signal produced; and quantitating the amount of substrate based on the signal. (Column 12, Claim 5).

Ikeda *et al.* teaches that the working electrode and counter electrode are on the same plane, and are in positions opposed to each other across a space. (Fig. 1)

Ikeda does not specify whether it is AC or DC current that supplies the potential to the working electrode, however since both positive and negative voltages are used in the working examples and it is known in the art that AC current can be either + or – while DC current is positive only that for purposes of examination the teachings of Ikeda *et al.* encompass both AC and DC currents.

Ikeda *et al.* teaches the use of a reference (third electrode) (Column 12, Claim 5).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This rejection is maintained for reasons of record set forth in the paper mailed 01/03/06, repeated below:

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (U.S. 6,340,428 B1) in view of Kuwabata *et al.* (2001), Crumbliss *et al.* (1986), Higgins (1987) and Ju *et al.* (1998).

The teachings of Ikeda *et al.* were discussed *supra.*

Ikeda *et al.* does not teach wherein a central potential of the AC potential is within the range of –0.4 to +0.4 V relative to a redox potential of said electron mediator, and is a potential more positive than a potential that is - 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled.

Ikeda *et al.* does not teach wherein a central potential of the AC potential being within the range of –0.1 to +0.1 V relative to a redox potential of said electron mediator, and is a potential more positive than a potential that is + 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the electric signal that is measured is impedance.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the working electrode is a rotating disk electrode or microelectrode.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the electron mediator is ferrocene carboxylic acid.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the oxidoreductase is pyrroquinoline quinone-dependent glucose dehydrogenase, and the electron mediator is ruthenium hexacyanate.

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.4 to 0.4 V (0.18 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.32 V), and is a potential that is –0.05 relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion controlled (Page 1, Lines 16-18 and Page 2, Line 20-25).

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.1 to 0.1 V (0.09 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.23 V), and is a potential that is 0.05 relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion controlled (Page 1, Lines 16-18 and Page 2, Line 20-25).

Kuwabata *et al.* teaches a method of quantitating a substrate in which the electric signal that is measured is impedance (Page 2, Lines 19-20).

Kuwabata *et al.* teaches a method of quantitating a substrate in which the oxidoreductase is glucose oxidase and the electron mediator is ferrocene carboxylic acid (Page 1, Lines 11-13).

Ju *et al.* teaches a method of quantitating a glucose in which the working electrode is a rotating disk electrode (Page 541, Column 2, Lines 18-19) or microelectrode (Page 541, Column 1, Lines 5-7).

Higgens teaches the use of pyrroquinoline quinine dependent glucose dehydrogenase in a method of quantitating a substrate in a liquid mixture (Column 4, Line 16-18).

Crumbliss *et al.* teaches the use of hexacyanoruthenate as an electron mediator in a reaction to quantitate a substrate (Page 327, Line 10).

One of ordinary skill in the art at the time of the instant invention would have been motivated to use a central potential within the range of –0.4 to +0.4 V relative to a redox potential of an electron mediator, that is a potential more positive than a potential that is -0.05 V relative to the most negative potential in a potential region where the reaction of an interfering reaction is diffusion-controlled because these ranges were demonstrated previously by Kuwabata *et al.* to provide a more precise measurement of the electron transfer process separated from the process of diffusion using AC current instead of the less precise and more prone to interference method using DC current.

One of ordinary skill in the art at the time of the instant invention would have been motivated to use a central potential within the range of –0.1 to +0.1 V relative to a redox potential of an electron mediator, that is a potential more positive than a potential that is 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering reaction is diffusion-controlled because these ranges were demonstrated previously by Kuwabata *et al.* to provide a more precise measurement of the electron transfer process separated from the process of diffusion using AC current instead of the less precise and more prone to interference method using DC current.

One of ordinary skill in the art at the time of the instant invention would have been motivated to use impedance because the technique was well known in the art and an advantage to using impedance biosensors is that they are not restricted to use solely with redox enzymes, allowing a greater range of proteins to be used in biosensor detection.

The ordinary artisan would have been motivated to use ferrocene carboxylic acid as an electron mediator in a redox reaction process using glucose oxidase because it was well known in the art that glucose oxidase was an oxidoreductase and that ferrocene derivatives were electron mediators, and that in the case where an electron mediator is required to be diffused throughout a solution it is desirable to use a more soluble ferrocene compound such as ferrocene carboxylic acid.

The ordinary artisan at the time of the instant invention would have been motivated to use microelectrodes or rotating disk electrodes in a method of quantitating a substrate because of the inherent advantages of using microelectrodes or rotating disk electrodes, such as being virtually free of fouling by interfering substance ascorbic acid and more rapid response time.

The ordinary artisan at the time of the instant invention would have been motivated to use pyrroquinoline quinine dependent glucose dehydrogenase or PQQ as the oxidoreductase and ruthenium hexacyanate as the electron mediator in a method of quantifying a substrate, because PQQ has the major advantage of not using oxygen as an electron acceptor, while ruthenium compounds were also known in the art as electron mediators and hexacyanoruthenate was shown to have the optimal characteristics of reversible electrochemistry at the electrode surface and rapidly oxidize an oxidoreducatase.

The ordinary artisan would have been motivated to combine the above teachings based on the advantages discussed above, resulting a in a faster, more precise measurement of electrochemical signal that would enable one of ordinary skill to more accurately measure an particular substrate in a sample even though the sample contained potential interferents. The ordinary artisan would have had a reasonable expectation of success based on the successful use of the techniques and compounds individually and their prior use in similar methods.

Applicant's arguments filed 04/03/06 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The Applicant argues that Ikeda discloses only a positive voltage applied to the working electrode and the negative voltage appears to be directed only to the third electrode. The claimed invention does not disclose the application of a negative voltage to the working electrode, merely that an AC potential is applied. Ikeda discloses the application of 500mV onto the working electrode in Column 6, Line 45.

Applicant alleges that the disclosed voltages would "more likely" be DC as opposed to AC because Ikeda's description of a negative voltage appears to imply DC current as AC would not appear to be described with a polarity. Using this argument, the application of 500mV to the working electrode would appear then to describe the application of AC voltage.

Nevertheless, as disclosed in the previous action, as known in the art AC potential can be either positive or negative while DC current is solely positive. Therefore the application of a negative potential (-1300mV) inherently demonstrates the presence of AC current being used in the reference.

Applicant states that because the disclosed voltages of 500mV and –1300mV are not applied simultaneously to the same electrode that it does not illustrate that the voltages are inherently AC. This reasoning is flawed for, as stated above, the presence of a negative potential is indicative of the presence of AC current. The burden of proving that is shifted to Applicant, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596(CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34(CCPA 1977)).

Applicant states that in Example 7 of Ikeda a potential of 500mV is applied to the third electrode and then changed to –1300mV, and alleges that this is apparently DC potential. As above, this line of reasoning is flawed by the presence of a negative voltage.

Applicant alleges that the word "potential" as used in the art generally means DC. As used in the art the term "potential" or "electric potential" is synonymous with voltage and as such can be applied equally to AC or DC current.

Regarding the Paragraph 103 rejection Applicant argues that Kuwabata only discloses an AC range rather than AC itself, which would not be obvious to one of ordinary skill in the art sufficiently to motivate one of ordinary skill to combine the references. The Examiner respectfully disagrees, as it would have been obvious to one of ordinary skill in the art that use of a range of AC currents would at the least, be obvious as denoting the use of AC current.

The Applicant states that Kuwabata only discloses the use of a sample including ferrocene carboxylic acid and glucose oxidase, dissolved in phosphoric acid buffer, with glucose added as a substrate. Further, Applicant states that Kuwabata does not disclose a sample containing an interfering substance as stated in the preamble of Claim 1 of the instant invention. In any event, Ikeda discloses the use of a sample containing interfering substances (Column 5, Lines 26-32) and the removal therein during the quantitation of an analyte.

It is deemed by the Examiner, in light of the teachings of Ikeda in view of Kuwabata, that the combination of the two references would have been obvious to one of ordinary skill in the art at the time of the invention based on the similarities between the two methods and one of ordinary skill in the art would have been motivated to do so in order to more reliable and accurately measure an analyte in a sample without the presence of interfering substances.

It is the view of the Examiner that one of ordinary skill in the art, in view of the teachings of Kuwabata and Ikeda (stated above), that one of ordinary skill could achieve all of the limitations of the instantly claimed invention.

Conclusion

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

04/21/06

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER